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Applicant's Name: Charles S. Schasteen et al.

Serial No.: 10/005,510 Examiner: V. Ford

Filing Date: 11/08/2001 Art Unit: 1645 Confirmation No.: 9657

Application Title: METHODS AND COMPOSITIONS FOR THE CONTROL OF COCCIDIOSIS

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NVI 5183.1
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Charles S. Schasteen et al. Art Unit 1645
Serial No.: 10/005,510
Filed: November 8, 2001
Confirmation No. 9657
For: METHODS AND COMPOSITIONS FOR THE CONTROL OF COCCIDIOSIS
Examiner Vanessa L. Ford

February 6, 2006

SUMMARY OF TELEPHONE INTERVIEW AND SUPPLEMENTAL RESPONSE TO OFFICE ACTION

TO THE COMMISSIONER FOR PATENTS,
SIR:

The telephone interview courteously granted by Examiner Ford and Supervisory Examiner Smith on April 5, 2006 is respectfully acknowledged.

Summary of Interview

Applicants' attorneys emphasized that claim 1 distinguishes the art with respect to features that are structural:

1. The claim requires that the vaccine be "substantially free of bacterial contaminats." This includes not only live bacteria but also non-viable bacteria and cellular debris. It is a purely structural limitation.

2. The claim characterizes the extent of freedom from bacterial contamination by a further structural feature that is defined in product-by-process language, i.e., it requires that such contaminants:

> "have been separated from said oocysts by tangential flow filtration of an aqueous process medium containing said oocysts and said bacterial contaminants using a filter membrane having a pore

> size such that sporulated oocysts cannot enter the pores, but said bacterial contaminants can pass through the pores."

That such further limitation is structural is reflected in the MPEP passage cited by applicants' undersigned attorney during the interview:

> "The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product." (MPEP §2113; emphasis supplied)

The filter membrane pore size as specified in the claim imparts such distinctive structural characteristic in characterizing the extent of freedom from bacterial contamination. As explained by Applicants' attorneys, the claim is equivalent in form to a claim specifying that the vaccine contains "not greater than x percent bacterial contamination." Instead of expressing the extent of exclusion of bacterial contamination in a numerical percentage, the claim does so by specifying a pore size that retains oocysts while allowing bacterial contaminants to pass through.

Since the outstanding rejections are predicated on the erroneous premise that instant claims are merely product-by-process claims that do not distinguish the art on structural bases, it is respectfully suggested that the explanation of the distinguishing structural features of the claim should lead to withdrawal of the rejections.

Applicants' attorneys also emphasized that there is no need for applicants to perform a side-by-side comparison of the composition of claim 1 and the compositions of Conkle, et al. or Evans, et al. Such a need could arise only if there were *prima facie* obviousness, which has not been shown, and even then, only if experimental evidence were necessary to establish a material difference from the prior art. Since there is a clear structural limitation in claim 1 that distinguishes both Conkle, et al. and Evans, et al., i.e., the substantial absence of bacterial contaminants, there is no need for a side-by-side comparison. Furthermore, applicants would be unable to perform a side-by-side comparison of the composition of claim 1 and the composition of Conkle, et al. since Conkle, et al. provides no disclosure of any specific pore size to use during filtration.

At the conclusion of the interview, the Examiners stated that the arguments presented by Applicants' attorneys would be taken under consideration.

Supplemental Response

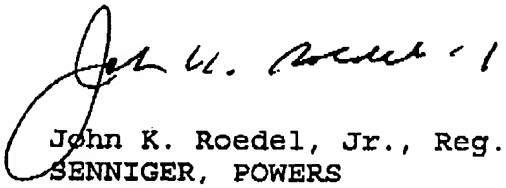
Discussion in the interview focused on the structural features of the claims. It should further be emphasized that separation of bacterial contaminants is neither taught nor suggested by the disclosures of Conkle and Evans with respect to sterilization and washing of oocysts:

1. Conkle separates wash water by tangential flow filtration, but fails to teach exclusion of bacterial contaminants because it does not teach or suggest using a filter membrane having a pore size that allows bacterial contaminants to pass through. Nor does it suggest or imply any purpose in doing so. For further discussion of the deficiencies of Conkle,

see Applicants' response of February 6, 2006 at page 5, lines 2-22.

2. Evans teaches the use of centrifugation for separation of wash water. It contains no teaching or suggestion that bacterial contaminants are transferred to the wash water. Since these are solids, the reasonable assumption is that they are retained in the oocycst fraction. For further discussion of the deficiencies of Evans, see Applicants' response of February 6, 2006 at page 19, line 5 to page 20, line 2.

Respectfully submitted,



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